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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GILEAD SCIENCES, INC.,

Plaintiff and Counterdefendant,

v.

MERCK & CO., INC. (Defendant only), MERCK SHARP & DOHME CORP. and ISIS PHARMACEUTICALS, INC.,

Defendants and Counterclaimants.

Case No. 5:13-cv-04057-BLF-PSG

DEFENDANTS' OPPOSITION TO GILEAD SCIENCES, INC'S MOTION TO COMPEL DEFENDANTS TO RESPOND TO DISCOVERY REQUESTS

Date: April 21, 2015
Time: 10:00 a.m.
Ctrm: 5, 4th Floor
Judge: Honorable Paul S. Grewal

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I. STATEMENT OF ISSUES TO BE DECIDED

1. Whether Defendants have met their obligations under Federal Rule of Civil Procedure 33 by providing answers to interrogatories (and supplementing those answers) that respond to those interrogatories to the extent they are relevant to the claims and defenses in this action, or whether Defendants were required to provide answers on issues that are irrelevant to any claim or defense in the action under governing Federal Circuit law?

2. Whether Defendants have met their obligations under Federal Rule of Civil Procedure 34 by producing documents in response to Gilead's document requests that are relevant to claims and/or defenses at issue in this case (in accordance with the limiting agreements reached by the parties during meet-and-confer sessions), or whether Defendants are required to produce documents that Gilead agreed not to demand and are, in any event, irrelevant to any claim or defense in the action under governing Federal Circuit law?

3. Whether Defendants have met their obligations under Federal Rule of Civil Procedure 30 by making the deposition witnesses identified by Gilead available for depositions on dates within the time period for fact discovery, which dates have in large part been accepted by Gilead, or whether (as Gilead contends) Defendants were required to provide multiple potential dates so that Gilead (represented by one of the largest intellectual property law firms in the United States) could pick and choose among various dates?

II. STATEMENT OF RELEVANT FACTS

A. Introduction

Defendant Merck & Co., Inc. and Defendants and Counterclaimants Merck Sharp & Dohme Corp. ("MSD") and Isis Pharmaceuticals, Inc. ("Isis") hereby oppose the Motion to Compel filed by Plaintiff Gilead Sciences, Inc. ("Gilead").

Gilead's motion should be denied for three reasons.

First, Gilead is failing to abide by agreements entered into by the parties to resolve Defendants' objections to Gilead's overbroad discovery requests concerning (a) synthesis of certain compounds (called "2'F-Me nucleosides" or "2'F-2'Me nucleosides") after the January 18, 2002

non-provisional filing date of the applications that ultimately issued as the patents-in-suit and concerning (b) post-2003 efforts to develop nucleosides for treatment of HCV that are outside the scope of the patents-in suit. For this reason, Gilead's motion to compel should be denied with respect to Document Requests 28, 39 and 60-62

Second, Gilead is seeking to compel discovery that is not related to the claims or defenses asserted in this action. For this reason, Gilead's motion to compel should be denied with respect to Interrogatories 1, 4 and 5 and Document Requests 46 and 49.

Finally, Gilead filed its motion to compel prematurely and before the meet-and-confer process had concluded with respect to interrogatories that Merck had agreed to supplement (and has now supplemented), depositions that Merck agreed to schedule (and which Merck has now scheduled or is in the process of scheduling), and documents that Merck had agreed to produce (and has now produced or is in the process of producing). For this reason, the remainder of Gilead's motion to compel should be denied.

B. Background and Status of This Litigation

This is a declaratory judgment action concerning two patents jointly owned by MSD and Isis (collectively, "Counterclaimants") that disclose and claim certain compounds, called "nucleoside analogs," that are useful for treating patients suffering from Hepatitis C Virus (HCV) infection. U.S. Patent No. 8,481,712 (the "'712 patent") is directed to specified nucleoside analogs that are effective against HCV. U.S. Patent No. 7,105,499 (the "'499 patent") is directed to methods of treating HCV by administering specified nucleoside analogs to infected patients.

The patents in suit each issued from non-provisional applications filed on January 18, 2002, and additionally claim the benefit of provisional applications filed in the preceding year. *See* Rabinowitz Ex. 1 ('499 patent, which issued on September 12, 2006 *directly* from the national phase of PCT Application No. PCT/US02/01531, filed January 18, 2002); Rabinowitz Ex. 2 ('712 patent, which issued on July 9, 2013 from non-provisional Application No. 10/052,318, filed January 18, 2002 through a chain of continuation and divisional applications, *without any intervening continuations-in-part*).

On April 3, 2015 the Court conducted a *Markman* hearing concerning the construction of one claim term ("administering") that is still disputed by the parties. (ECF No. 120). An additional claim term ("compound") was previously disputed but, in the days leading up to the *Markman* tutorial held on March 30, 2015 (ECF No. 118), Gilead formally withdrew its proposed construction and agreed that this term has the meaning proposed by Defendants. (ECF No. 113). In conceding the construction of "compound," Gilead has effectively admitted that the '712 patent is infringed by the accused pharmaceutical products that Gilead sells for treating HCV infections. Additionally, it is Defendants' expectation that after claim construction is completed, infringement of the asserted claims from the '499 patent will also be established. These questions of infringement are directly relevant to Counterclaimants' forthcoming motion to compel Gilead to produce complete copies of the New Drug Applications ("NDAs") by which Gilead sought and obtained FDA approval to market its sofosbuvir-containing products, SOVALDI and HARVONI. Counterclaimants have repeatedly requested these documents, which Gilead has repeatedly refused to produce.

Having retreated from any claim construction position that could have supported a non-infringement position with respect to the '712 patent, Gilead is pressing for discovery that, under established Federal Circuit precedent, has no relevance to the grounds of invalidity that Gilead has pleaded in this action.

The close of fact discovery in this case was originally scheduled for April 24, 2015. On March 20, 2015, the Court granted a stipulated Order extending the fact discovery cutoff date to May 22, 2015. (ECF No. 112).

C. Gilead Has Ignored Agreements Reached In The Meet-And-Confer Process To Limit Its Discovery Demands

Gilead purports to recount the relevant procedural history in the first twelve pages of its motion, but has either ignored or simply failed to acknowledge many of the most relevant facts. First, Gilead has literally ignored the agreements that were reached during the course of the meet-and-confer process to limit its overbroad and unduly burdensome discovery demands. Defendants engaged in this process in good faith, but Gilead's actions demonstrate a failure to adhere to its agreements.

1. Gilead Has Ignored Its Agreement To Limit Its Demand For Discovery Of 2' Fluorinated Compounds Without Date Restriction To Discovery of 2'F-Me Nucleosides Through December 31, 2006

Gilead's requests for production initially sought production and description of every compound that Defendants considered or tested "containing fluorine at the 2' position." *See* Gilead's First Requests for Production Of Documents No. 28 ("all Documents relating to any 2'-modified nucleoside compounds for HCV treatment . . ."); No. 39 (similar) (Rabinowitz Decl. Ex. 3); Gilead's Second Request For Production of Documents No. 60 ("All Documents relating to Merck and/or Isis's synthesis, attempted synthesis, or hypothesized synthesis of nucleoside compounds with a fluorine at the 2' "down" position and a C_{1-4} alkyl group, including methyl, at the 2' "up" position."), 61 & 62 (similar) (Rabinowitz Decl. Ex. 4). These demands were not only overbroad in scope, they were unlimited with respect to time.

Defendants repeatedly informed Gilead that these discovery demands were improper, unduly burdensome and not properly tailored to focus on documents that were relevant to any claim or defense at issue in this case. (Rabinowitz Decl. ¶ 6). For example, during the meet and confer on February 10, 2015, Defendants informed Gilead that Defendants had produced documents relating to the synthesis of 2'F-Me nucleosides (as opposed to all 2' F compounds) and had done so for the period through the end of 2004. Defendants explained that it was their belief that the proper cut-off for such documents was January 18, 2002 (the filing date of the non-provisional applications that ultimately issued as the patents-in-suit). Defendants further explained that they had, as a compromise, produced documents covering the period ending December 31, 2004 in an attempt to accommodate Gilead's demands. Defendants further stated that they were willing to produce such documents for the period through the publication of Gilead's patent application on January 13, 2005 (the "Clark Application"), which, in other proceedings, Gilead had relied on as enabling a person of ordinary skill in the art to make such compounds. Defendants further explained that the requested documents should be limited to 2'F-Me nucleosides, as opposed to all 2' F compounds, since Gilead was relying on the proposition (as it does in its Motion to Compel) that 2'F-Me compounds are "very difficult to synthesize" and could not be made by persons of ordinary skill in the art until

Gilead's predecessor, Pharmasset, published the Clark Application on January 13, 2005 teaching how to make such compounds. *See* Motion to Compel at 3.

In a letter dated February 12, 2015 (Warden Ex. O), Gilead retreated from its prior demand for all 2' fluorinated compounds, and now sought production of documents relating to all 2'F-Me nucleosides. Gilead, however, continued to press for discovery without any date cutoff.

In a letter dated February 25, 2015 (Warden Ex. R), Defendants offered as a further compromise to produce documents relating to the synthesis of 2'F-Me documents through December 31, 2006. Defendants explained that these documents would disclose synthesis of "no fewer than nine (9) 2'F-Me nucleoside analogs."

> In your February 12, 2015, letter, you claim that Defendants' synthesis of 2'F-Me nucleosides after publication of the Clark application are relevant to enablement, written description, and derivation. We disagree that Defendants' synthesis of 2'F-Me nucleosides without limitation as to time are relevant to Gilead's defenses. Gilead cannot use the discovery process as a fishing expedition. As discussed, documents concerning Defendants' synthesis of 2'F-Me nucleosides beyond January 13, 2005, which is the publication date of the Clark application, are not relevant to Gilead s defenses. However, in the spirit of compromise, Defendants are willing to produce documents related to Defendants' synthesis of 2'F-Me nucleosides until December 31, 2006, which disclose synthesis of no fewer than nine (9) 2'F-Me nucleoside analogs. We believe such discovery would be more than sufficient to address the ostensible reasons for your discovery request. Please confirm that this compromise is acceptable to Gilead.

Warden Ex. R at 2.

By letter dated March 4, 2015, Gilead ***accepted*** Defendants' proposed compromise to limit production to 2'F-Me nucleoside analogs made through December 31, 2006. (Warden Ex. S). Gilead's counsel wrote:

> We accept Defendants' proposal to produce all documents related to synthesis of 2'F-Me nucleosides up until December 31, 2006, with the understanding that Defendants will produce documents related to any efforts—successful or not, including commentary, discussions, and conclusions related to such efforts—and not just documents related to successful synthesis.

Warden Ex. S at 1. That agreement was further documented by letter dated March 24, 2015 from Defendants' counsel to Gilead, which stated: "During our meet and confer, you confirmed that Gilead has accepted Defendants' proposal regarding a December 31, 2006 cutoff date for documents relating to the synthesis of 2'F – 2'Me nucleosides." (Rabinowitz Decl. Ex. 5 at 1). This letter,

reciting the agreements reached at the March 23, 2015 meet-and-confer, crossed with Gilead's instant Motion to Compel and accordingly was not included among the 24 exhibits that Gilead appended to its moving declaration.

On April 3, 2015, Defendants produced the agreed-upon documents. Those documents bear Bates Numbers MERCK0176511 to MERCK0176765. (Rabinowitz Decl. Ex. 6).

Notwithstanding the agreement of the parties to limit these discovery requests, Gilead has moved to compel production in response to Document Requests 28, 39, 60, 61 and 62 as if it had never entered into such an agreement.

2. Gilead Has Ignored Its Agreement To Limit Discovery To Defendants' Lead Compounds

Gilead's discovery requests initially sought disclosure of all documents related to Defendants' research and development of compounds for HCV treatment from 2000 – 2011, but those requests were narrowed by agreement during the meet-and-confer process. Specifically, Gilead's Document Request No. 46 sought:

> All Documents relating to Defendants' research and development of compounds for HCV treatment from 2000 – 2011, including boceprevir.

(Warden Ex. A); *see also* Gilead's Document Request No. 49.

During the course of the ensuing discussions between Gilead and Defendants, Defendants made it clear that this request was unduly burdensome and not calculated to lead to the discovery related to any claim or defense at issue. The parties finalized an agreement to limit discovery on this topic during their meet-and-confer session on March 23, 2015 to lead compounds identified by Defendants for the treatment of HCV, and Defendants' counsel disclosed that there was only such lead compound (MK-0608). That agreement was documented in the letter from Defendants' Counsel to Gilead's Counsel dated March 24, 2015:

> The parties have agreed that Merck will produce documents concerning lead compounds that fall within the scope of the claims, the structural formulas or the examples in the specification, sufficient to disclose why such compounds were selected for development and why such development was discontinued. As discussed, MK-0608 is the only compound in this category.

(Rabinowitz Decl. Ex. 5). Notwithstanding the agreement to the contrary, Gilead has moved to compel production under Request Nos. 46 and 49.

D. Gilead's Interrogatories Nos. 1, 4 and 5

Gilead's Interrogatory No. 1 seeks discovery of *Defendants' contentions* regarding the date of invention. In their Supplemental Response, dated March 5, 2015, Defendants made it perfectly clear that they are relying solely on two acts of constructive reduction to practice: the filing of a provisional application on June 19, 2001 and the filing of non-provisional applications on January 18, 2002, and that they are not relying on dates of conception other than these dates of reduction to practice. (Rabinowitz Decl. Ex. 7 at 5:4-9). Defendants have answered fully and completely regarding what they contend is the date of invention and regarding the acts of constructive reduction to practice on which they are relying to establish that date.

With respect to Interrogatories Nos. 4 and 5, which inquire about embodiments of the invention that Defendants have made, used or tested, Gilead is purportedly seeking evidence to support its defenses that the claimed subject matter supposedly lacks a supporting written description, is not enabled by the specification, and was derived from Gilead's predecessor. As discussed below, settled precedent makes clear that those defenses are adjudged based upon the disclosure in the specification *as of the filing date* of the application in question.

Defendants have objected to these interrogatories to the extent they seek information about making, using or testing compounds after the January 18, 2002 filing date, have reiterated that Defendants are not relying on any actual reduction to practice prior to the January 18, 2002 filing date, and expressly stated that "prior to January 18, 2002, [Defendants] did not make, use or test any operable embodiment of the subject matter defined by the asserted claims of the [patents-in-suit]." (Rabinowitz Decl. Ex. 8 at 4:25 to 5:9 and 6:4-6).

Now that Gilead has insisted on burdening the Court with its meritless motion, Defendants ask the Court to apply clear Federal Circuit law and hold that the materials post-dating the January 18, 2002 filing date for the non-provisional patent applications that ultimately issued as the patents-in-suit are not relevant to any claim or defense in the instant litigation.

E. Gilead Has Prematurely Moved To Compel, Notwithstanding The Fact That Defendants Stated That They Would Make Supplemental Disclosure

During the meet-and-confer session on March 23, 2015, Defendants informed Gilead that they would supplement their responses to Interrogatories Nos. 2, 8, 10 and 11. (Rabinowitz Decl. Ex. 5 at 2) ("With respect to Interrogatories Nos. 2, 8, 10 and 11, Defendants will supplement their responses to these interrogatories by April 8, 2015, as discussed.") During that meet-and-confer, Defendants explicitly informed Gilead that they did not believe that the meet-and-confer process had been fully utilized, and that any threatened motion to compel was premature. In its motion to compel, Gilead admits that it was informed by Defendants that supplemental responses to these interrogatories would be forthcoming "within two weeks" (Motion at 9, lines 4 – 7), but does not disclose that Defendants explicitly stated that the meet-and-confer process was ongoing.

On April 8, 2015, Defendants served Gilead with supplemental responses to Interrogatories 2, 7, 8, 10 and 11. (Rabinowitz Decl. Ex. 9) These supplemental responses render moot Gilead's motion to compel on these topics.

F. Gilead Has Ignored The Efforts That Defendants Have Undertaken To Provide Dates For The 16 Noticed Depositions, Including Those Of (a) Current High-Ranking Executives and Scientists and (b) 10 Former Employees

Gilead's motion to compel inaccurately asserts that Defendants have failed to accommodate Gilead's requests for cooperation in arranging for the depositions of noticed witnesses. Gilead has noticed 16 depositions. (Rabinowitz Decl. Ex. 12; s*ee also id*. Ex. 5 & 11). Ten of those noticed deponents (MacCoss, Ashton, Durette, Walton, Kender, Pomerantz, Pon, Song, Cook and Eldrup) are no longer employees of Defendants. The noticed deponents who are current employees of Defendants include senior executives and scientists, whose activities are scheduled long in advance. Nonetheless, Defendants have arranged for many of those noticed deponents, including former employees to travel to convenient locations in New York or California at Defendants' expense so that their depositions can occur without need for the parties' attorneys to travel to the state of residence of each individual deponent. Moreover, Defendants have arranged for those noticed deponents to make themselves available during the fact discovery period. Deposition dates have been agreed for six of the noticed depositions (Carroll, MacCoss, Ashton, Bhat, Prakash and Cook)

and Defendants have provided Gilead with proposed dates for an additional six depositions (Durette, Walton, Demain, de Laszlo, Kender and Pomerantz). (Rabinowitz Decl. Ex. 12) Of the remaining four depositions, Defendants expect to provide dates for two (Olsen and Pon) within a week, one deponent (Eldrup) is a former employee who lives overseas, and one (Song) is a former employee for whom Defendants are still attempting to obtain current contact information. To the extent that multiple dates can be provided (consistent with the availability of the witness and the relevant attorneys), Defendants are doing so. In the end, Gilead's true objection is that "It is unacceptable to Gilead for Defendants to refuse to produce witnesses on the dates noticed by Gilead and to not offer multiple dates for its witnesses." (Motion at 14, lines 18 – 19). That is no basis for a motion to compel.

G. Gilead Has Ignored Defendants' Extensive Efforts To Provide Comprehensive Responses To Its Burdensome Discovery Demands

Gilead's contention that Defendants have failed to undertake reasonable efforts to provide discovery is likewise without factual basis. Gilead complains about the time Defendants required to provide substantive responses to certain of Gilead's discovery demands, without acknowledging the extreme burden that those demands placed on Defendants. For example, Defendants informed Gilead repeatedly that Interrogatories Nos. 4, 5 & 6, by demanding disclosure regarding all operable embodiments (Interrogatory No. 4) or "any testing . . . of compounds that fall within the claims of the Patents-in-Suit" (Interrogatory No. 5) or "the synthesis and biological activity of all compounds containing fluorine at the 2' position made or tested by or on behalf of Defendants" (Interrogatory No. 6) required extensive and burdensome archival research through the laboratory records of both Merck and Isis. (Rabinowitz Decl. ¶ 12). Gilead also demanded that Defendants "[d]escribe in complete detail all biological assay testing performed by or on behalf of Defendants of all 'representative compounds' referenced in [the specification of the patents-in-suit]." (Interrogatory No. 15). Through the dedication of significant resources, Defendants obtained comprehensive answers and provided them in their Supplemental Responses and Objections To Plaintiff's Interrogatories Nos. 1, 4-6 and 15 on March 5, 2015. (Rabinowitz Decl. Ex. 7). Those Supplemental Responses catalog the extensive work that Defendants undertook, including the

disclosure in Appendix A of the structure, internal Merck identifier, and laboratory notebooks providing data on each of one hundred twenty-six (126) separate representative compounds referenced in the specification.

H. Defendants' Document Production

As discussed hereinafter, Defendants' document production has been or will soon be fully complete insofar as it is relevant to the claims and defenses in this action.

III. ARGUMENT

A. Defendants Have Fully Satisfied Their Obligations in Responding to Gilead's Interrogatories

1. Interrogatories 1, 4 and 5 Seek Information That Is Not Relevant to the Claims and Defenses in This Action

a. Interrogatory No. 1 Has Been Answered Completely

Plaintiff's Interrogatory No. 1 seeks a description of the factual and legal basis and supporting evidence for what *Defendants' contend* to be the date of the invention for each claim of the patents-in-suit, including the identification of individuals involved in the conception or reduction to practice of each claim of the patents-in-suit.

There can be no doubt that Defendants have fully and completely set forth their *contention* on this issue. On March 5, 2015, Defendants provided a supplemental response to this interrogatory stating: "The subject matter of each and every claim asserted in this action was constructively reduced to practice on (a) on June 19, 2001 by filing Provisional U.S. Patent Application No. 60/282,069, and (b) on January 18, 2002 by filing U.S. Application No. 11/701,682 and International Application No. PCT/US02/01531 designating the United States." (Rabinowitz Decl. Ex. 7 at 5). Defendants further responded that the factual basis was set forth subpart E in their response to Interrogatory No. 14. *See id*.

Given that Defendants are relying on a constructive reduction to practice for the date of invention, Defendants' response to this interrogatory is sufficient and complete. Gilead has contended in its motion, discovery correspondence and during meet-and-confer sessions that it seeks this information to support its contentions that the patents-in-suit are invalid for (i) lack of written

description and (ii) lack of enablement. Plaintiff has no basis for demanding that Defendants rely on or disclose a reduction to practice other than the act of filing patent applications, where Defendants rely solely on the content of the applications they filed and do not seek to establish an earlier date of invention.

It is well-established that "the act of filing the United States application has the legal effect of being, constructively at least, a simultaneous conception and reduction to practice of the invention." *Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998) (quoting *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed.Cir.1986)). "There is no need for proof or corroboration of the subject matter that is included in the application unless a date earlier than the filing date is sought to be established." *Hyatt*, 146 F.3d at 1352 (citing *Yasuko Kawai v. Metlesics*, 480 F.2d 880, 886 (CCPA 1973)). "Thus the inventor need not provide evidence of either conception or actual reduction to practice when relying on the content of the patent application." *Hyatt*, 146 F.3d at 1352. Therefore, as stated above, Gilead's overly broad and unduly burdensome request for information related to actual reduction to practice – where Defendants rely solely on a constructive reduction to practice - is legally irrelevant to the claims and defenses in this action.

Defendants respectfully submit that the Court should deny Gilead's motion to compel additional disclosure in response to Interrogatory No. 1. Defendants have fully responded insofar as this interrogatory is relevant to any claim or defense at issue in this case.

b. Amended Interrogatory Nos. 4 and 5 Have Been Answered To The Extent They Seek Relevant Information

Gilead's Amended Interrogatory No. 4 seeks a description of every operable embodiment of any claim of the patents-in-suit that Defendants have made, used, and/or tested and, for each such compound, a description as to when the compound was conceived and reduced to practice, and the results of any testing on each compound including without limitation assays for the inhibition of HCV NS5B Polymerase, the inhibition of HCV RNA replication, **without limit as to time**. Similarly, Gilead's Amended Interrogatory No. 5 seeks a description of any testing of compounds that fall within the class defined by the structural formula set forth in the claims of the patents-in-suit, including the method used, any testing of compounds containing fluorine at the 2' position,

when the testing of those compounds began, criteria for determining which compounds were active, and identification of those compounds considered active, **without limit as to time**. During the parties' meet-and-confer discussions, Gilead insisted that it was entitled to the requested information ***for any time period, including any testing in 2015, long after the patents-in-suit were issued and even after commencement of this action***.

Defendants have objected to these interrogatories as overbroad and irrelevant (a) to the extent they concern claims not asserted in this action, and (b) to the extent they seek information about making, using, or testing compounds after the January 18, 2002 filing date of the non-provisional applications that ultimately issued as the patents-in-suit. Insofar as they are relevant to the claims and defenses in this action, Defendants have expressly stated that prior to January 18, 2002, they did not make, use or test any operable embodiment of the subject matter defined by the asserted claims of the patents-in-suit and did not, before that date, test any compounds within the classes defined by the structural formulas set forth in the asserted claims of the patents-in-suit. *See* Rabinowitz Decl., Ex. 8 at 5:1-3, 5:7-9, and 6:4-6.

During the parties' meet-and-confer discussions, Gilead contended that the requested information about activities after the January 18, 2002 filing date is relevant to Gilead's defenses of lack of written description, non-enablement, and derivation. *See also* Gilead's Motion to Compel at 15-16 (same). Under settled precedent, the post-filing information is irrelevant.

As the Federal Circuit has clearly explained: "[T] he test for sufficiency of the written description is whether the disclosure *of the application relied on* reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter *as of the filing date*." *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (emphasis added). The test for written description requires "an objective inquiry *into the four corners of the specification* from the perspective of a person of ordinary skill in the art." *Id*. (emphasis added). Moreover, "the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement." *Id*. at 1352 (citing *Falko-Gunter Falkner*

v. Inglis, 448 F.3d 1357 (1366-67 (Fed. Cir. 2006)). It is simply irrelevant to written description what the inventors (or Defendants' other scientists) did after the January 18, 2002 filing date of the application that Defendants rely on. Post-filing activities can neither add to nor detract from the objective disclosure of the application as filed in January 2002, which is what counts for written description.

Nor are the requested post-filing activities relevant to Gilead's non-enablement defense. On the contrary, enablement depends on what the *specification*, teaches to those skilled in the art of the patent. "To be enabling, *a patent's specification* must 'teach those skilled in the art to make and use the full scope of the claimed invention without "undue experimentation."'" *Streck, Inc. v. Res. & Diag. Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) (quoting *ALZA Corp. v. Andrx Pharm. LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010)) (internal citation omitted in original) (emphasis added). "The enablement requirement is met where one skilled in the art, *having read the specification*, could practice the invention without 'undue experimentation.'" *Id*. (quoting *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)) (emphasis added). Here again, it is the objective disclosure of the specification that counts for enablement.

Gilead's reliance on *Plant Genetic* for the contrary proposition is misplaced. In that case, it was held that the use of post-filing ***publically available information*** could be relevant to describe what was known as the state of the art to one of skill in the art, at the time of filing the patent application. *Plant Genetic Sys., N.V. v. Dekalb Genetics Corp.*, 315 F.3d 1335, 1343-44 (Fed. Cir. 2003). Defendants' internal, confidential information is not the post-filing ***publically available information*** that could be useful to show the state of the art at the time of filing of a patent application and is therefore irrelevant to the enablement or written description of the patents-in-suit. The vast overbreadth of Gilead's discovery request is demonstrated by Gilead's attempt to reach activities conducted *as of today*, more than a year a half after filing the complaint in the instant litigation and well after the patents-in-suit were issued. Gilead's discovery request would force Merck to engage in expensive and irrelevant fact discovery. Gilead has failed to set forth a legal

basis as to why Defendants' synthesis and testing of compounds after the January 18, 2002 filing date is relevant to written description or enablement.

With respect to Gilead's allegation of derivation, the information requested is likewise irrelevant. "In order to establish derivation [Gilead is] required to 'prove both *prior* conception of the invention by another and communication of that conception to the patentee.'" *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1313 (Fed. Cir. 2011) (quoting *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1334 (Fed. Cir. 2003)) (emphasis added). Gilead does not allege (nor could it) that ***any information*** was communicated to Defendants before Defendants' filing date of January 18, 2002. Under settled precedent, post-filing communication of Gilead's information ***cannot be relevant*** to a claim of derivation. If the January 18, 2002 applications, as filed, both describe and enable the claimed subject matter, it is simply irrelevant whether the claims were amended or prosecuted with Gilead's product in mind. On the other hand, if the January 18, 2002 applications, as filed, fail to describe the subject matter of an asserted claim or fail to enable the subject matter of an asserted claim, that claim is invalid for that reason

As the Federal Circuit has long held, "there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application." *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988). Under *Kingsdown*, it is irrelevant whether or not the asserted claims were amended after January 18, 2002 for the reasons alleged by Gilead. If the claimed subject matter is described and enabled by the January 2002 application, such amendment is expressly authorized under *Kingsdown*. And if either written description or enablement is lacking, the claim in question is invalid for that reason. Defendants should not have to comply with the overly burdensome "fishing expedition" that Gilead seeks to conduct in support of a proposition that is legally irrelevant to the question of validity.

In light of the case-law cited above, and Defendants' reliance on constructive reduction to practice, Interrogatories Nos. 4 and 5 are overly broad, unduly burdensome, and seek information not relevant to the claims or defenses of any party, especially since they seek information beyond the January 18, 2002 filing date of the applications that ultimately issued as the patents-in-suit. Defendants have answered these interrogatories fully and completely to the extent seek information relevant to the claims and defenses in this action.

2. Defendants' Supplemental Responses Moot Gilead's Motion To Compel With Regard To Interrogatory Nos. 2, 7, 8, 10 And 11

At the March 23, 2015 meet and confer between Merck and Plaintiff, Merck indicated that Interrogatories Nos. 2, 8, 10 and 11 would be supplemented by April 8, 2015. Merck stated during that meet and confer that that forthcoming supplementation rendered Gilead's threatened motion premature. As noted above, that supplemental information has now been provided, along with supplemental information in response to Interrogatory No. 7. Thus, Plaintiff's assertion that Defendants' responses to Gilead's Interrogatories Nos. 2, 7, 8, 10 and 11 are deficient under Rule 33(d) is now moot.

For all of the reasons articulated hereinabove, Plaintiff's Motion to Compel in respect to Interrogatory Nos. 2, 7, 8, 10 and 11 should be denied.

B. Gilead's Motion Demands Production Of Documents In Contravention Of Gilead's Agreements

Gilead's motion ignores the agreements that it reached to limit these discovery demands during the course of meet-and-confer sessions. Specifically, Gilead agreed to limit its requests to information regarding synthesis of "2' F-Me nucleosides" during the period up to December 31, 2006. The documents disclosing that information were produced to Gilead on April 3, 2015. Those documents disclose the synthesis of nine separate compounds that are "2' F-Me nucleosides", fully addressing any contention of lack of enablement. Moreover, as noted above, the adequacy of the written description of the specification of the patents-in-suit must be adjudged based upon the four corners of the specification, not later performed experiments (or even previously performed work that was not disclosed or referenced in the specification).

Gilead's motion further ignores the agreement the parties reached during the meet-and-confer process concerning the production of information regarding work by Merck on compounds that are (a) lead compounds that (b) fall within the scope of the claims, the structural formulas or the examples in the specification of the patents-in-suit. The parties have agreed that Defendants will disclose information sufficient to identify (1) why such compounds were selected for development and (2) why such development was discontinued. Defendants further have disclosed to Gilead that there was only one "lead compound" during the relevant period, which was given the internal identification code MK-0608.

Notwithstanding the parties' agreements, Gilead seeks to compel document production regarding compounds that (1) were ***not*** lead compounds that fall within the scope of the claims, the structural formulas or the examples in the specification of the patents-in-suit; and 2) are ***not*** 2'F-Me nucleosides synthesized prior to December 31, 2006. As noted above, agreements have been reached with regard to the production of documents meeting these two criteria. The documents that Gilead seeks to compel concern compounds that are irrelevant to the issues in this case, as demonstrated by the agreements reached by the parties.

To the extent that Gilead seeks to have this Court compel Merck to produce documents that it has already agreed to produce, that motion is both premature and improper. Merck has already produced copious documents, and is assiduously working to complete its document discovery. Gilead has continued to serve new requests for production, most recently on February 20, 2015. Once this Court rules on the scope of the remaining document production, Merck expects to be able to complete document discovery by the first week of May.

C. Defendants Are Cooperating In Scheduling the Depositions Requested by Gilead

Gilead has requested that the depositions be scheduled of sixteen individuals. As discussed in Section II(F), above, ten are former employees over whom the Defendants have no control. During the parties' meet-and-confer discussions, Defendants assured Gilead that they would cooperate to provide deposition dates, and they are doing so. To date, deposition dates have been agreed for six of the requested deponents and Defendants have offered dates for an additional six

depositions. (Rabinowitz Decl. Ex. 12). Defendants expect to provide dates for a further two deponents within a week. The two remaining depositions requested by Gilead are of one former employee who lives overseas and another former employee for whom Defendants are still attempting to obtain current contact information.

Gilead's demands for multiple potential dates for the depositions of these witnesses are not a proper basis for a motion to compel. Many of the deponents identified by Gilead are high level corporate officials or scientists, who have limited availability, or former employees, who have other commitments and who are not under Defendants' control. Gilead, understandably, agreed to put off the depositions of these witnesses until document production was near completion. Given the large numbers of witnesses involved, their competing professional obligations, and the attempt not to "double track" depositions, Defendants' proffered dates are reasonable and adequate. Moreover, Gilead's contention that its counsel should not be asked to meet this schedule rings hollow, given that (1) Gilead actually has agreed to six of these dates, (2) Gilead is represented in this matter by Fish & Richardson, which has ample resources to manage the schedule, and (3) Gilead's legal team includes at one dozen attorneys (including four partners) who regularly send or receive correspondence on this matter and are on the ECF system. Simply put, Gilead's counsel have adequate staff to meet the scheduled depositions.

IV. CONCLUSION

In view of the above, Defendants respectfully requests that the Court deny, in its entirety, Plaintiff's Motion to Compel.

Dated: April 8, 2015

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CERTIFICATE OF SERVICE

I certify that all counsel of record are being served on April 8, 2015 with a copy of this document via the Court's CM/ECF system.

/s/ Stephen S. Rabinowitz
STEPHEN S. RABINOWITZ